

CLAIMS

What is claimed is:

1. A method of immunotherapy to treat cancer by administering an effective
5 amount of a natural cytokine mixture (NCM) including cytokines selected from the
group consisting essentially of IL-1, IL-2, IL-6, IL-8, IL-12, IFN- δ , TNF- α , GM-
CSF, G-CSF, recombinants thereof, and combinations thereof.
2. The method according to claim 1, wherein said administering step is
defined as administering 75 to 500 units IL-2 equivalence.
- 10 3. The method according to claim 1, wherein said administering step is
defined as bilaterally administering the NCM into lymphatics that drain into lymph
nodes.
4. The method according to claim 1, wherein said administering step is
defined as unilaterally administering the NCM.
- 15 5. The method according to claim 1, wherein said administering step is
defined as administering the NCM for at least 1 to 10 days.
6. The method according to claim 5, wherein said administering step is
further defined as administering the NCM up to about 20 days.
7. The method according to claim 6, wherein said administering step is
20 further defined as administering the NCM bilaterally and for about 10 days.
8. The method according to claim 1, wherein said administering step is
defined as administering the NCM prior to surgery or radiotherapy.
9. The method according to claim 1, wherein said administering step is
defined as administering the NCM during recurrence of tumors.
- 25 10. The method according to claim 1, further including the step of
administering an effective amount of cyclophosphamide (CY).
11. The method according to claim 1, further including the step of
administering an effective amount of a nonsteroidal anti-inflammatory drug
(NSAID) selected from the group consisting of indomethacin (INDO), Ibuprofen,
30 celecoxib (Celebrex®), rofecoxib (Vioxx®), CoxII inhibitors, and combinations
thereof.

12. A method of immunotherapy to treat cancer by administering an effective amount of CY and an effective amount of INDO.

13. A synergistic anti-cancer treatment method by administering an effective amount of CY and an effective amount of NSAID selected from the group
5 consisting essentially of indomethacin (INDO), Ibuprofen, celecoxib (Celebrex®), rofecoxib (Vioxx®), CoxII inhibitors, and combinations thereof.

14. A method of immunotherapy to treat cancer by administering an effective amount of CY in combination with an effective amount of INDO and an effective amount of IFN- δ , IL-2, IL-1, and TNF- α .

10 15. A method of immunotherapy to treat cancer by administering an effective amount of CY in combination with an effective amount of INDO and an effective amount of recombinant IL-2, recombinant IFN- δ , recombinant TNF- α , and recombinant IL-1.

16. A synergistic anti-cancer treatment comprising the steps of administering an
15 effective amount of CY and INDO in combination with an NCM including cytokines selected from the group consisting essentially of IL-1, IL-2, IL-6, IL-8, IL-12, IFN- δ , TNF- α , GM-CSF, G-CSF, recombinants thereof, and combinations thereof.

17. A synergistic anti-cancer composition comprising an effective amount of
20 CY; an effective amount of INDO; and an effective amount of an NCM including cytokines selected from the group consisting essentially of IL-1, IL-2, IL-6, IL-8, IL-12, IFN- δ , TNF- α , GM-CSF, G-CSF, recombinants thereof, and combinations thereof.

18. An anti-metastatic treatment method comprising the steps of promoting
25 differentiation and maturation of immature dendritic cells in a lymph node; allowing presentation by resulting mature dendritic cells of antigen to T-cells to gain immunization of the T-cells to the antigen; and preventing development of metastasis.

19. An anti-metastatic method by unblocking immunization at a lymph node;
30 and generating systemic immunity.

20. The anti-metastatic method according to claim 19, further including the step of preventing development of metastasis.

21. A method of using a natural cytokine mixture as a diagnostic skin test for predicting treatment outcome by administering an NCM intracutaneously and
5 determining a response to the NCM within 24 hours, wherein a negative skin test indicates unresponsiveness to the NCM and predicts failure of patients to respond to surgery with or without radiotherapy.

22. A method of pre-treatment of dendritic cells (DC) by applying an effective amount of CY and INDO in combination with an NCM including cytokines
10 selected from the group consisting essentially of IL-1, IL-2, IL-6, IL-8, IL-12, IFN- δ , TNF- α , GM-CSF, G-CSF, recombinants thereof, and combinations thereof.

23. A method of treating monocyte defects characterized by sinus histiocytosis or a negative NCM skin test by applying an effective amount of CY and INDO in combination with an NCM including cytokines selected from the
15 group consisting essentially of IL-1, IL-2, IL-6, IL-8, IL-12, IFN- δ , TNF- α , GM-CSF, G-CSF, recombinants thereof, and combinations thereof.

24. A method of eliciting an immune response to tumor antigens by administering an effective amount of an NCM including cytokines selected from the group consisting essentially of IL-1, IL-2, IL-6, IL-8, IL-12, IFN- δ , TNF- α , GM-
20 CSF, G-CSF, recombinants thereof, and combinations thereof.

25. The method according to claim 24, wherein the tumor antigens are selected from the group consisting essentially of endogenous and exogenous tumor antigens.

26. A method of eliciting an immune response to tumor antigens by
25 administering an effective amount of an NCM; and an effective amount of CY, wherein the NCM includes cytokines selected from the group consisting essentially of IL-1, IL-2, IL-6, IL-8, IL-12, IFN- δ , TNF- α , GM-CSF, G-CSF, recombinants thereof, and combinations thereof.

27. The method according to claim 26, wherein the tumor antigens are selected from the group consisting essentially of endogenous and exogenous tumor antigens.

5 28. A method of eliciting an immune response to tumor antigens by administering an effective amount of an NCM; an effective amount of CY; and an effective amount of INDO, wherein the NCM includes cytokines selected from the group consisting essentially of IL-1, IL-2, IL-6, IL-8, IL-12, IFN- δ , TNF- α , GM-CSF, G-CSF, recombinants thereof, and combinations thereof.

10 29. The method according to claim 28, wherein the tumor antigens are selected from the group consisting essentially of endogenous and exogenous tumor antigens.

30. A composition for eliciting an immune response to endogenous or exogenous tumor antigens comprising an effective amount of an NCM including cytokines selected from the group consisting essentially of IL-1, IL-2, IL-6, IL-8,
15 IL-12, IFN- δ , TNF- α , GM-CSF, G-CSF, recombinants thereof, and combinations thereof.

31. The composition according to claim 30, wherein said composition further comprises an effective amount of CY.

20 32. The composition according to claim 31, wherein said composition includes an effective amount of INDO.